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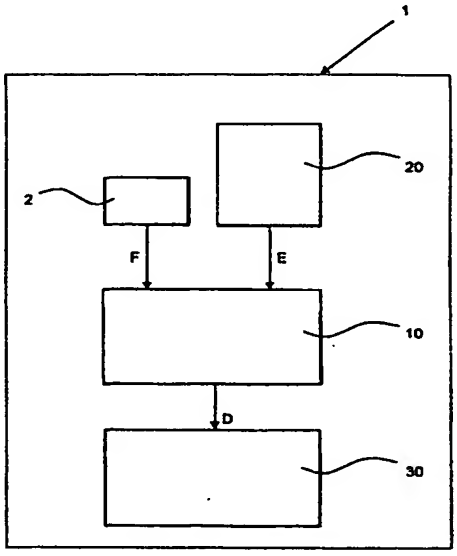

(57) Abstract: A medical implant (1) comprising oscillator monitoring means (10) for monitoring the function of an oscillator (2) in the medical implant, and a method of monitoring the function of an oscillator (2) in a medical implant (1). The oscillator (2) produces periodic pulses for use in the operation of the medical implant (1), and the oscillator monitoring means (10) detects a deviation in the function of the oscillator (2) and provides a deviation signal (D) indicating the detection of such a deviation. The medical implant (1) also comprises measuring means (20) for obtaining a physiological parameter emanating from the human body. The measuring means (20) is also provided for generating an electric signal (E) related to a time component of the physiological parameter, and the oscillator monitoring means (10) is connected to the measuring means (20) and uses the electric signal (E) for the deviation detection.

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MEDICAL IMPLANT

Technical field of the invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to a medical implant comprising oscillator monitoring means for monitoring the function of oscillator means in the medical implant, and a method of monitoring the function of oscillator means in a medical implant, said medical implant preferably being a heart stimulator.

Technical background and prior art

For modern electronic circuits, it is generally essential to provide an accurate clocking signal in order to synchronise the different electronic functions of the circuit. Generally, a single master timing source, such as an oscillator, is used to produce a periodic signal at a fixed frequency. An accurate clock signal is imperative for a proper function of the electronic circuit. If the frequency of the periodic signal deviates from its predetermined frequency, the circuit will not function in the intended manner.

Within the field of medical implants, i.e. heart stimulators, the master timing source is generally an oscillator. Heart stimulators are life supporting, therapeutic medical devices that are surgically implanted and remain within a person's body for years. Thus, a need exists for monitoring and checking the master oscillator of the heart stimulator to determine if the frequency of the oscillator periodic signals deviates from its predetermined clock frequency and to handle such deviation if it occurs.

US 4,590,941 discloses a cardiac pacer comprising stimulating logic for producing an output stimulating signal, the stimulating logic including a crystal os-

cillator and a digital circuit for producing the pacing logic of the pacer. The pacer further comprises a continuously operating RC oscillator and a frequency checking circuit. The RC oscillator is an emergency oscillator continuously producing an output at a predetermined acceptable frequency and a predetermined pulse width. The crystal frequency is tested by the frequency checking circuit using the output of the RC oscillator. The pacer further comprises gating means for substituting the output of the RC oscillator for the output of the stimulating logic upon detection of failure of the crystal oscillator.

Hence, the reference parameter used for continuously testing the frequency of the crystal oscillator is the output frequency of the RC oscillator. This requires a continuous operation of the RC oscillator. Furthermore, the frequency checking circuit requires a reliable output from the RC oscillator in order to provide a safe and accurate result. Otherwise, the frequency of the crystal oscillator could be considered to deviate from the correct frequency when, in fact, it is the frequency of the RC oscillator that deviates from the predetermined frequency.

Summary of the invention

It is therefore an object of the present invention to provide a method, and a medical implant using said method, for detecting with improved reliability a frequency deviation of the output frequency of an oscillator in a medical implant.

This object is achieved in accordance with the present invention by providing a medical implant and a method having the features defined in the independent claims. Preferred embodiments are defined in the dependent claims.

The invention is based on using a physiological parameter emanating from the human body for monitoring the

status of the output frequency of a timing circuit in a medical implant. Hence, deviations in the output frequency of the timing circuit are detected by using the physiological parameter as a reference. Preferably, the timing circuit is an oscillator.

By using a physiological parameter for detecting a deviation in the output frequency of an oscillator, use is made of a parameter that is always present, i.e. the physiological parameter can be used for detecting a frequency deviation regardless of whether there is a fault in the electronic circuitry or not. This might not always be the case when a parameter obtained from within the electronic circuitry is used for said deviation detection. In fact, a deviation in the output frequency of a main oscillator in an electronic circuit, can cause resulting effects in the electronic circuitry making components within the circuitry unsuitable, or unusable, for providing a reference parameter for said monitoring.

Furthermore, the problem described in relation to prior art regarding the risk of misinterpreting the result, i.e. the output frequency one oscillator being considered to deviate when the deviation occurs in the output frequency of the other oscillator, is eliminated according to the present invention. This is due to the fact that the monitoring of an oscillator does not involve any other oscillator that might be comprised in the medical implant.

The physiological parameter used for the monitoring of the output frequency of the oscillator contains a time component. The time component of the physiological parameter is used for monitoring deviation of the frequency from a permitted value or range.

As is obvious to a person skilled in the art, any physiological parameter varies over time. Therefore, an exact time value can not be obtained from a physiological parameter. However, the typical oscillator used as a

main oscillator in a medical implant is a crystal oscillator, which is calibrated before encapsulation through mechanical treatment. It is well known that, if the output frequency of a crystal oscillator deviates from its intended frequency, it deviates drastically, the output frequency for instance changing to zero or multiples of the intended frequency. Thus, a physiological parameter can be used for monitoring the status of an oscillator, even though said parameter varies slightly over time.

Further details and aspects of the invention will become apparent from the following detailed description of embodiments of the invention, reference being made to the accompanying drawings.

Brief description of the drawings

Figure 1 illustrates in block diagram form a medical implant comprising oscillator monitoring means according to the present invention.

Figure 2 illustrates in block diagram form the measuring means shown in figure 1.

Figure 3 illustrates in block diagram form the monitoring means shown in figure 1.

Figure 4 illustrates in block diagram form a specific embodiment of the present invention.

Figure 5 illustrates in circuit diagram form a watch dog circuit according to the embodiment shown in figure 4.

Detailed description of preferred embodiments

With reference to figure 1, there is shown in block diagram form a medical implant 1 comprising an oscillator 2, oscillator monitoring means 10, measuring means 20 and deviation handling means 30. As apparent to the person skilled in the art, a medical implant, i.e. a heart stimulator, comprises and is connected to a number of additional elements that are essential for the intended function of the implant, e.g. a pulse generator,

telemetry means, etc. However, the functions of these elements are well known within the art and the illustration and description thereof are therefore omitted. Thus, only parts of the medical implant directly related to the present invention are illustrated and described herein.

As illustrated in figure 2, the measuring means 20 preferably comprises sensor means 21, for sensing, or recording, a chosen physiological parameter P, and detecting means 25, for detecting characteristics of the chosen physiological parameter P. The sensor type can be chosen among several alternatives and is dependent on the chosen physiological parameter P. The sensor means 21 is connected to the detecting means 25, but is not necessarily contained within the medical implant 1, contrary to what is illustrated in figure 1. According to embodiments of the invention, the sensor means 21 is situated externally of the medical implant and is connected to the medical implant through electric leads (not shown).

The detecting means 25 is arranged for detecting characteristics of the physiological parameter P comprising the chosen time component, the characteristics being dependent on the type of parameter sensed, and for generating an electric signal E containing or being related to these characteristics. The sensor means 21 and the detector means 25 do not necessarily have to be separate units, instead they can be comprised as a single unit for sensing the physiological parameter P and for generating the electric signal E.

With reference to figure 3, the oscillator monitoring means 10 preferably comprises signal processing means 11, receiving the electric signal E and oscillator output frequency F (i.e. the periodic pulses produced by the oscillator), and comparing means 15, receiving an oscillator status signal S supplied by the signal proc-

essing means 11 and a predetermined reference signal Ref, which can be in the form of a value, range, or a template. Preferably, the electric signal E representative of the physiological parameter P is used by the signal processing means 11 for generating an oscillator status signal S that reflects the status of the oscillator output frequency F.

The oscillator status signal S can be directly indicative of the output frequency F, e.g. by representing the number of pulses produced by the oscillator 2 during a chosen time interval, or be indirectly indicative of the output frequency F, e.g. by presenting a signal representing a parameter, which in turn is directly dependent on the output frequency F.

The oscillator status signal S is supplied to the comparing means 15 for comparing the status signal S with a predetermined reference signal Ref. The reference signal used for said comparison could be a value, a range or a template of some sort, depending on the nature of the physiological parameter. As a result of said comparison, a deviation signal D is produced indicating whether the output frequency of the oscillator is within a permitted value or range, or not.

Preferably, the oscillator status signal S is in the form of a value representing the output frequency F of the oscillator, and the reference signal Ref is in the form of two threshold values representing the permitted maximum and minimum frequencies of the oscillator. In such a case, the deviation signal D preferably has two possible values, the output frequency F lies within the permitted range, or the output frequency F is outside the permitted range. According to an alternative embodiment, the oscillator status signal S represents the morphology of a physiological parameter P, e.g. heart sounds, and the comparing means 15 compares the oscillator status signal S to a template using neural

networks. Several other alternatives regarding the form of the oscillator status signal S and the reference signal Ref are conceivable without departing from the scope of the present invention.

According to preferred embodiments of the present invention, the physiological parameter P used for the monitoring of the status of the oscillator 2 is the electrical signal emitted by active cardiac tissue, which for ease of description hereinafter will be referred to as the cardiac signal C. The cardiac signal C is typically recorded through cardiac electrodes and the graphic depiction of the signal is normally referred to as an electrocardiogram (ECG). If the electrodes are placed on or within the heart, the graphic depiction is referred to as an intracardiac electrogram (IEGM). The characteristic portions of the ECG or IEGM are very well known and will be referred to without further description in detail.

The time component used for the oscillator monitoring preferably is obtained within a cardiac cycle, particularly within the systolic phase thereof. The physiological parameters could for instance be related to the width of the QRS-complex or to the QT-interval (i.e. related to the ejection phase of the heart). The parameters related to the width of the QRS-complex preferably is derived from the IEGM by means well known in the art. The parameters related to the QT-interval may be derived directly from the IEGM or indirectly by means of pressure measurements in the ventricle, by impedance measurements, by means of heart sounds such as the valve sounds. Corresponding methods are well known in the art. Said comparison is preferably performed repeatedly for achieving a continuous monitoring of the oscillator status using the IEGM or corresponding parameters of the latest heart beat.

With reference to figures 4 and 5, the most preferred embodiment of the present invention will now be described. The cardiac electrical activity (i.e. the cardiac signal C) is sensed through at least one cardiac electrode 22 positioned within the patient's heart. The sensed parameter is supplied, now in the form of an IEGM, to the detecting means 25, in this case constituting a QRS detector 26 and a T-wave detector 27 that both receives the IEGM. The QRS detector 26 detects the QRS complex, i.e. the R-peak, and the T-wave detector 27 consequently detects the T-wave. The detectors 26, 27 generate a QRS-detector output signal Q and a T-wave detection signal T, respectively, in the form of a short pulse when the respective event is detected.

The chosen time component of the physiological parameter P used for said monitoring is in this case the time period between the QRS complex and the T-wave of the IEGM, said time period hereinafter being referred to as the QT-interval. The QT-interval is relatively easy to measure and use is preferably made of the existing cardiac electrode(s) used for stimulating (and sensing) in the ventricle for sensing the QRS complex and the T wave. The QT-interval typically varies within the range of 250 to 350 ms and is substantially independent of the output of the main oscillator. There may be some, but very small, correlation since the QT-interval depends upon the stimulation rate. The QT-interval is therefore very useful and is preferred as the physiological parameter used for said monitoring.

Returning to figure 4, the electric signal E, being divided into the QRS detection signal Q and a T-wave detection signal T, is supplied via a watch dog circuit 40 to the signal processing 11, the signal processing means 11 here being a counter 12. The watch dog circuit 40 is provided between the detecting means 25 and the counter 12 for handling a specific situation and will be de-

scribed in detail below with reference to figure 5. The function of the counter 12 is as follows. The counter 12 will be reset by a QRS event, i.e. a pulse in the QRS detection signal Q. The pulse will also trigger the counter 12 to start counting received periodic pulses F produced by the main oscillator 2. At the reception of a pulse in the T-wave detection signal T, the counter 12 will stop counting and the counted number of received pulses during the QT-interval will be sent as the oscillator status signal S to the comparing means 15.

The QT-interval will then be compared, by the comparing means 15, with predefined QT-interval threshold values provided by a reference signal Ref, corresponding to the QT-interval at the maximum and minimum, respectively, permitted main oscillator frequency. The T-wave detection signal T is also provided to the comparing means 15 via a delay circuit 50 for triggering said comparison. The delay circuit 50 ensures that sufficient time has elapsed for the calculation to be completed before the triggering of the comparison. The result of the comparison will be supplied as a deviation signal D indicating whether the output frequency F of the oscillator 2 lies within the permitted range, or not.

With reference now to figure 5, the function of the watch dog circuit 40 will be described. If no signal for triggering the comparison and providing a deviation signal, i.e. the T-wave detection signal T, is provided to the comparing means 15, no comparison would be carried out and the information contained in the deviation signal D would not change to describe the current status, provided that the oscillator status has changed. One attempt to solve this problem could be to perform a comparison after a given time delay without reception of the T-wave detection signal T. However, this would require some sort of timing signal to be provided. If no output pulses are received from the oscillator 2 this

would not be indicated in the deviation signal D if no T-wave detection signal T for triggering the comparison is received from the T-wave detector, i.e. if the patient has no intrinsic rate.

In order to solve this potentially serious problem, the watch dog circuit 40 is provided. The watch dog circuit 40 is provided for delivering a pulse after a predetermined time in the absence of a QRS detection signal Q and a T-wave detection signal T. The circuit 40 comprises a first resistor 41; a second resistor 42; a transistor 43; a capacitor 44; a first buffer circuit 45; a second buffer circuit 46; a first OR-gate 47; and a second OR-gate 48. As is apparent from the figure, when a QRS detection signal Q or a T-wave detection signal T, respectively, are received, these signals are supplied via the respective OR-gates 47, 48 as QRS detection signal Q^I and T-wave detection signal T^I, respectively. The respective detection signals Q, T passes the watch dog circuit essentially unchanged, even though the output detection signals Q^I, T^I supplied to the comparing means have a difference reference character in the figure.

If there would be a no QRS detection signal Q, there would be no T-wave signal T. If there is a QRS signal, there will be a T-wave signal. Thus, the situation to be considered is the loss of both the QRS and the T-wave detection signals. The capacitor 44 is connected to ground and will be charged by the voltage supplied via the second resistor 42. The time constant of the circuit is dependent of the second resistor 42 and the capacitor 44. The charging of the capacitor 44 increases the potential of the side connected to the first buffer circuit 45. When the potential reaches a predefined level, the buffer circuit 45 goes high. If a QRS detection signal Q is supplied to the watch dog circuit 40, this will cause the transistor 43 to short-circuit

and discharge the capacitor 44 and the potential of the first buffer circuit 45 will drop to zero before the first buffer circuit 45 goes high. However, if no QRS detection signal Q is supplied, a pulse is supplied by the first buffer circuit 45 to the first OR-gate 47 and, via the second buffer circuit 46, to the second OR-gate 48.

Then, the pulse will be supplied in place of the QRS and T-wave detection signals Q^I, T^I to the counter, with a slight delay for the T-wave detection signal T^I caused by the second buffer circuit 46, and a low pulse count, corresponding to the delay caused by the second buffer circuit 46, will be sent to the comparing means 15 as the status oscillator signal S. The T-wave detection signal T^I will also trigger the comparison. Since the value of the status oscillator signal S will not lie within the predefined permitted range, the deviation signal D will indicate that the output frequency F of the oscillator has deviated from the permitted range.

According to another embodiment of the present invention the width of the QRS complex is measured and used for said monitoring. The variation of the QRS width is somewhat greater than that of the QT-interval. Like the QT-interval, this parameter can easily be measured using the cardiac electrode(s) and requires no additional electronic circuitry. Preferably, the number of output pulses from the oscillator to be monitored is counted, preferably using counting means 12 comprised in the signal processing means 11, during the duration of the QRS, and is supplied as an oscillator status signal S.

Another example of using the IEGM for said monitoring is using the paced depolarisation integral (PDI). The PDI is a well-known parameter that denotes the integral of the QRS complex of the IEGM from the base line. The PDI essentially is constant from beat to beat. Pref-

erably, PDI is obtained using integrating means comprised in the signal processing means 11. In similarity with the above embodiments, using the PDI requires no additional sensors (e.g. electrodes) or circuitry. The variation of the PDI corresponds with the QRS width, and the obtained value of the PDI is supplied as the electric signal E, as illustrated in figure 3. Since the calculated value of the PDI varies in dependence on the output frequency F, the oscillator status signal S is based on the electric signal E, comprising the PDI value, and the output frequency F. The integral is calculated by means of the output frequency and the value of the PDI will deviate from the normal value if the frequency deviates from the standard value. If the oscillator status signal S is determined to be outside predetermined threshold values, this will indicate that the oscillator frequency deviates from the permitted range.

Other physiological parameters are envisioned for monitoring the status of the main oscillator 2. According to one alternative embodiment the physiological parameter is the heart sounds or sound waves produced when the heart operates, e.g. sounds associated with valve opening and closing and diastolic filling sounds. As is the case with the characteristics of the ECG or the IEGM, the sound waves correspond to specific events in the cardiac cycle and have a characteristic morphology. Thus, the time information obtained from heart sounds is considered to be as accurate, or vary as little, as the QT-interval.

The morphology may be analysed in several ways. According to a first example of alternative embodiments of the present invention, the number of pulses output by the oscillator between detected specific events in the sound waves of the cardiac cycle is counted and supplied

as an oscillator status signal S for subsequent comparison with threshold values Ref.

There are several ways of detecting heart sounds, including using a microphone or an accelerometer. The advantage of using an accelerometer is that accelerometers are often used in rate responsive heart stimulators for determining the level of physical activity of the patient. Thus, such an accelerometer could also be used for detecting heart sounds, and no additional sensor means would be required. If the heart sounds are detected by a microphone, however, then an additional component that normally is not found in a medical implant or heart stimulator is used. There may also be a problem in detecting the heart sounds as distinctly as is required for determining the time for specific events of the cardiac cycle, due to the interference of the external environment.

According to preferred embodiments of the invention, the medical implant comprises a back-up timing circuit (not shown), preferably an oscillator, for acting as a main timing circuit, or oscillator, when the output frequency of the original main oscillator 2 deviates outside the predefined permitted range. The back-up oscillator is preferably an RC oscillator, or a current controlled oscillator, for the purpose of providing a back-up timing source that is small and light in weight.

As is shown in figure 1, deviation handling means 30 is connected to the monitoring means 10, preferably to the comparing means 15, for handling a deviation in the output frequency F of the main oscillator 2. The handling means 30 is activated when the received deviation signal D indicates a deviation, i.e. when the output frequency F deviates outside the permitted range. The handling means 30 comprises the back-up oscillator (not shown), for producing periodic pulses normally not being used in the operation of the medical implant, and

switching circuitry (not shown) connected to the main and the back-up oscillator for switching between the normal state and a deviation state. The switching between the respective state is performed by disconnecting the main oscillator 2 and by simultaneously connecting the back-up oscillator such that the periodic pulses produced in the back-up oscillator are used in the operation of the medical implant. According to preferred embodiments of the invention, the status of the back-up oscillator is also monitored by the monitoring means of the present invention, in the manner described above. However, since the back-up oscillator is normally not used for the normal function of the medical implant, the monitoring of the back-up oscillator can be performed regularly but at a substantially lower rate than the monitoring of the main oscillator, which should be performed continuously.

According to an alternative embodiment of the invention, the deviation handling means 30 comprises alarm means for providing an alarm signal when the deviation signal D indicates that the output frequency F of the oscillator 2 deviates outside the permitted range. The alarm signal could be in the form of a signal that can be observed or sensed by the patient, e.g. an acoustic signal, or a signal that is transmitted to an external apparatus using the telemetry functions generally provided in a medical implant. The alarm signal could be provided in combination with said switching to the back-up oscillator, or as a separate action, e.g. indicating that the patient should contact his/her physician but that the need for switching to the back-up oscillator has not arisen. A detected deviation in the output frequency of the back-up oscillator, when functioning as such, is preferably handled by the handling means 30 activating an alarm signal. Switching to the other oscillator will not be necessary since the back-up oscillator

in this case is not involved in the normal operation of the medical implant.

The timing circuits used in the medical implant according to present invention are preferably oscillators, wherein as the main oscillator use is preferably made of a crystal oscillator, due to the superior reliability of crystal oscillators.

CLAIMS

1. A medical implant (1) comprising oscillator monitoring means (10) for monitoring the function of oscillator means (2) in the medical implant (1), said oscillator means (2) producing periodic pulses for use in the operation of the medical implant (1), said oscillator monitoring means (10) detecting a deviation in said function and providing a deviation signal (D) indicating said deviation detection; and

measuring means (20) for obtaining at least one physiological parameter (P) emanating from the human body, said parameter comprising a time component, and for generating an electric signal (E) related to said time component, said oscillator monitoring means (10) being connected to the measuring means (20) for using said electric signal (E) for said deviation detection.

2. The medical implant (1) according to claim 1, wherein the monitoring means (10) comprises signal processing means (11) for processing the electric signal (E) and for generating an oscillator status signal (S), and comparing means (15) for comparing said oscillator status signal (S) with a reference signal (Ref).

3. The medical implant (1) according to claim 2, wherein said measuring means (20) comprises sensor means (21) for sensing the physiological parameter (P).

4. The medical implant (1) according to claim 3, wherein the sensor means (21) comprises cardiac electrodes (22) for receiving cardiac signals (C) emanating from cardiac electrical activity, said cardiac signals (C) constituting the physiological parameter (P) and being representative of the time component and forming an IEGM.

5. The medical implant (1) according to claim 4, wherein said measuring means (20) comprises detector

means (25) connected to the sensor means (21) for detecting the QRS complex and the T-wave of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS detection signal (Q), and a T-wave detection signal (T).

6. The medical implant (1) according to claim 5, wherein said signal processing means (11) comprises counting means (12), said counting means (12) being connected to said detector means (25) for receiving the QRS and the T-wave detection signals (Q, Q^I, T, T^I), and to said oscillator means (2) for receiving the periodic pulses,

said counting means (12) being arranged for counting the number of periodic pulses received between the reception of the QRS detection signal (Q, Q^I) and the T-wave detection signal (T, T^I), and for outputting said number as said oscillator status signal (S).

7. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS signal indicating the beginning and the end of the QRS complex; and

said signal processing means (11) comprises counting means (12) connected to said detector means (25) for receiving the QRS signal, and to said oscillator means (2) for receiving the periodic pulses, said counting means (12) being arranged for counting the number of periodic pulses received between the beginning and the end of the QRS complex, and for outputting said number as said oscillator status signal (S).

8. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex and the amplitude of theQRS, and for generating said electric signal (E); and

said signal processing means (11) comprises integrating means connected to said detector means (25) for receiving the electric signal (E), said integrating means being arranged for integrating said amplitude during the QRS complex, and for outputting said integration as said oscillator status signal (S).

9. The medical implant (1) according to claim 3, wherein

the sensor means (21) comprises at least one microphone for converting sensed periodic heart sounds into an electric periodic sound signal, said heart sounds constituting the physiological parameter (P);

the measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting chosen characteristics of the sound signal, and for generating said electric signal (E) indicating said characteristics; and

the signal processing means (11) is arranged for outputting said oscillator status signal (S) based on said electric signal (E).

10. The medical implant (1) according to any one of claims 2-9, wherein the reference signal (Ref) comprises predefined threshold values, and wherein the monitoring means (10) provides the deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

11. The medical implant (1) according to any one of the preceding claims, comprising deviation handling means for handling a deviation in said oscillator means, said deviation handling means being connected to said

monitoring means (10) for reception of said deviation signal (D).

12. The medical implant (1) according to claim 11, wherein said deviation handling means comprises

a back-up system including back-up oscillator means for producing periodic pulses, said periodic pulses in a normal state not being used in the operation of the medical implant (1), and

switching circuitry connected to said main and back-up oscillator means for switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

13. The medical implant (1) according to claim 12, wherein said monitoring means (10) further is arranged for detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating the detection of such a deviation, and wherein said deviation handling means is arranged for handling a deviation in said back-up oscillator means.

14. The medical implant (1) according to claim 12 or 13, wherein said back-up oscillator means is an RC oscillator.

15. The medical implant (1) according to any one of claims 11-14, wherein said deviation handling means comprises alarm means for producing an alarm signal when the received deviation signal (D) indicates a deviation.

16. The medical implant (1) according to any one of the preceding claims, wherein said oscillator means (2) is a crystal oscillator.

17. A method of monitoring the function of oscillator means (2) in a medical implant (1), preferably a heart stimulator, the method comprising

obtaining at least one physiological parameter (P) emanating from the human body, said physiological parameter (P) containing a time component; and

using said physiological parameter (P) in monitoring the function of said oscillator means.

18. The method according to claim 17, wherein the step of monitoring said function comprises

detecting a deviation in said function; and

providing a deviation signal (D) indicating said deviation detection.

19. The method according to claim 17 or 18, wherein the step of obtaining said physiological parameter (P) comprises

sensing said physiological parameter (P); and

generating an electric signal (E) based on said physiological parameter (P); and

wherein the step of detecting said deviation comprises

processing the electric signal (E) and thereby generating an oscillator status signal (S); and

comparing said oscillator status signal (S) with a reference signal (Ref).

20. The method according to any one of claims 17-19, wherein said physiological parameter (P) is a cardiac signal (C) emanating from cardiac electrical activity, said cardiac signals (C) being representative of the time component and forming an IEGM.

21. The method according to claim 20, wherein the step of processing the electric signal (E) comprises

detecting the QRS complex of the IEGM;

detecting the T-wave of the IEGM;

receiving periodic pulses from said oscillator means;

counting the number of received periodic pulses between said detection of the QRS complex and said detection of the T-wave; and

outputting said number as the oscillator status signal (S).

22. The method according to any one of claims 19-21, wherein said reference signal (Ref) comprises predefined threshold values; and

wherein the step of comparing said oscillator status signal (S) with a reference signal (Ref) comprises

providing a deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

23. The method according to any one of claims 18-22, further comprising the steps of

receiving the deviation signal (D) provided by the comparing means (15);

handling a deviation in said oscillator means (2) when the received deviation signal (D) indicates a deviation.

24. The method according to claim 23, wherein the step of handling a deviation comprises

activating a back-up system comprising back-up oscillator means for generating periodic signals, said periodic signals in an normal state not being used for the operation of the implant; and

switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

25. The method according to claim 24, further comprising the steps of

detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating detection of such a deviation; and

handling a deviation in said back-up oscillator means.

26. The method according to any one of claims 24-25, wherein the step of handling a deviation comprises activating an alarm signal.

Fig. 1

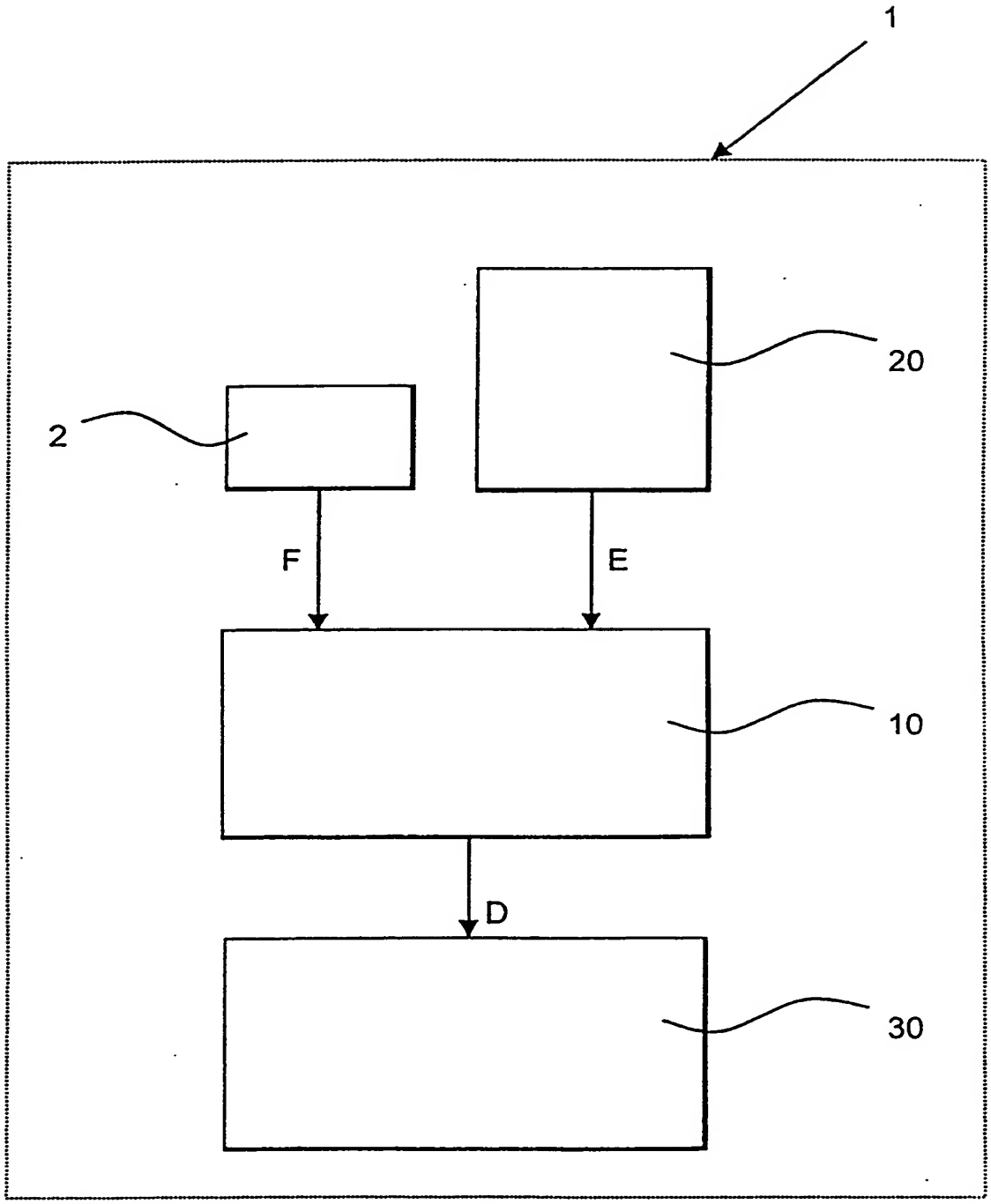


Fig. 2

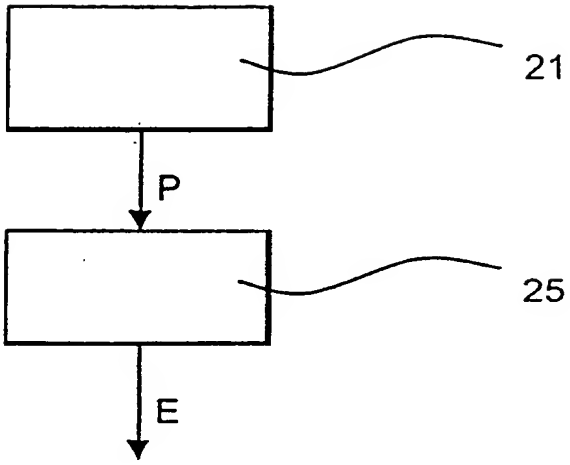


Fig. 3

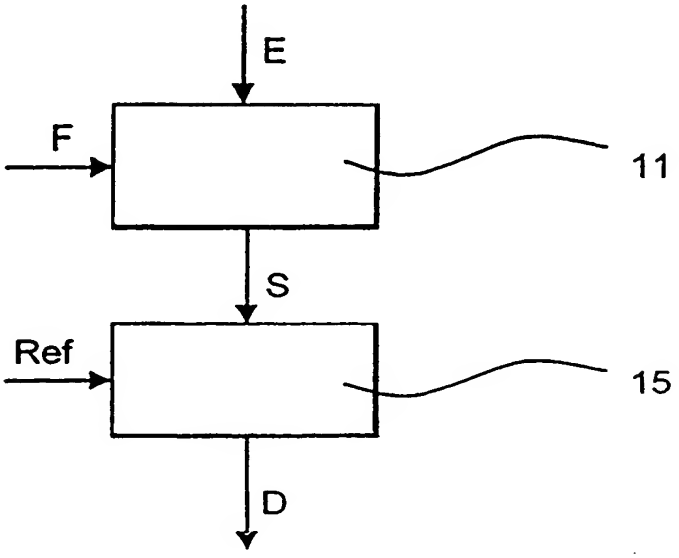


Fig 4

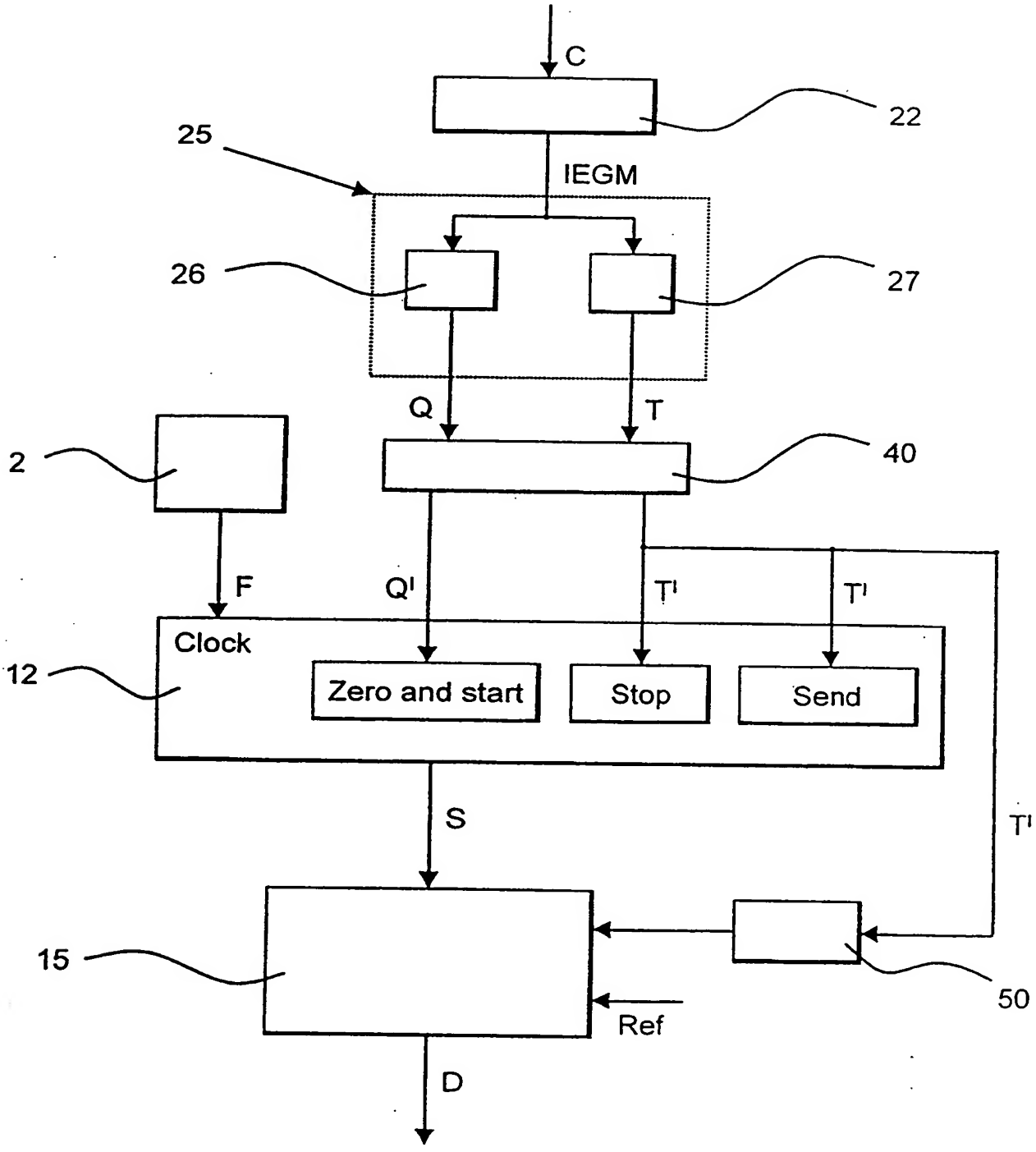
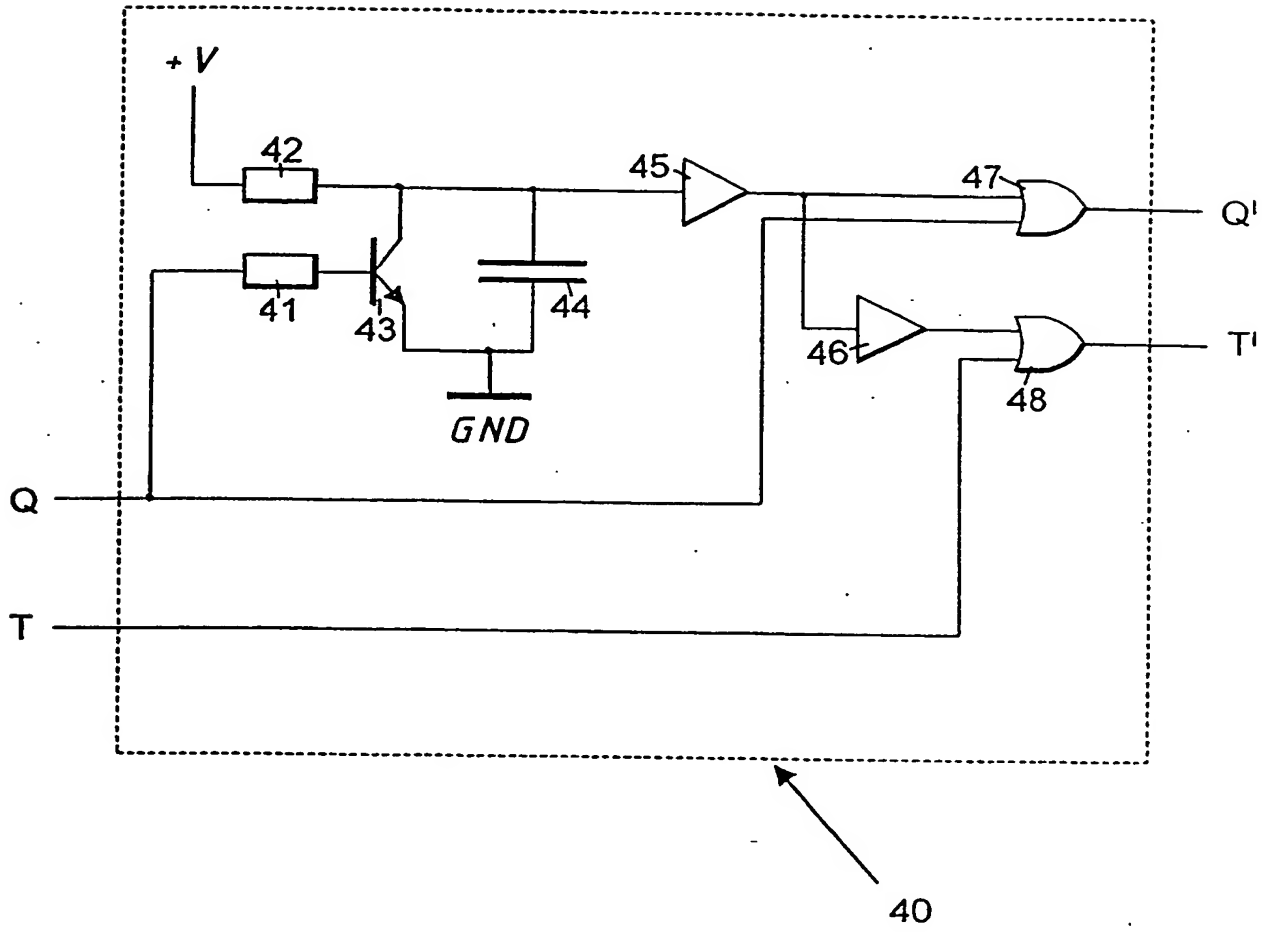

C
22
25
IEGM
26
27
Q
T
2
40
F
Q'
T'
T'
Clock
12
Zero and start
Stop
Send
S
T'
15
50
Ref
D

Fig.5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01025

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 1599231 A (MEDTRONIC INC.), 30 Sept 1981 (30.09.81), page 2, line 1 - line 23	1-26
A	DE 2539592 A1 (INFORM ELEKTROMEDIZINISCHE GERÄTE GMBH), 10 March 1977 (10.03.77), page 1, line 1 - page 2, line 15	1-26
D,A	US 4590941 A (STANLEY H. SAULSON ET AL), 27 May 1986 (27.05.86), abstract	1-26

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 Sept 2000	19 -09- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/mj Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/00

International application No.
PCT/SE 00/01025

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 1599231 A	30/09/81	AR 224616 A	30/12/81
		AU 519527 B	10/12/81
		AU 3645478 A	29/11/79
		BE 868057 A	02/10/78
		BR 7803758 A	09/01/79
		CA 1101935 A	26/05/81
		DE 2825626 A,C	21/12/78
		FR 2394281 A,B	12/01/79
		IT 1105721 B	04/11/85
		IT 7849827 D	00/00/00
		JP 1356909 C	13/01/87
		JP 54006388 A	18/01/79
		JP 61025387 B	16/06/86
		NL 7806336 A	15/12/78
		SE 439732 B,C	01/07/85
		SE 7806319 A	14/12/78
		US 4164945 A	21/08/79
DE 2539592 A1	10/03/77	FR 2322616 A	01/04/77
US 4590941 A	27/05/86	US 4437466 A	20/03/84

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

2

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
99 P 2009 P		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE00/01025	22/05/2000	03/06/1999
International Patent Classification (IPC) or national classification and IPC A61N1/365		
Applicant St.JUDE MEDICAL AB		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/10/2000	28.06.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Krahbichler, E Telephone No. +49 89 2399 7365

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/01025

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-15	as originally filed

Claims, No.:

1-26	as received on	11/06/2001	with letter of	08/06/2001

Drawings, sheets:

1/4-4/4	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 17 - 26.

because:

   ☒ the said international application, or the said claims Nos. 17 - 26 relate to the following subject matter which does not require an international preliminary examination (*specify*):
   see separate sheet

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Yes: Claims 1 - 16

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1 - 16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1 - 16
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Reference is made to the following document:

D1: US-A-4590941

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Independent **claim 17** describes a method in a medical implant comprising the step of obtaining a physiological parameter emanating from the human body. The measurement of the physiological parameter, preferably an intracardial electrogram (see description, page 7, lines 5 to 15), is done inside the human body. Although it is not mentioned explicitly in the claim, it is regarded that the described method involves inherently the step of implanting the device in the human body.
Claim 17 appears thus to relate to a surgical method as mentioned in Rule 67.1(iv) PCT for which no preliminary examination needs to be carried out (see Article 34(4)(a)(i) PCT).

Claims 18 to 26 define further preferred steps of the method of claim 17 and thus also no preliminary examination needs to be carried out for these dependent claims.

Re Item V

Reasoned statement with regard to **novelty, inventive step or industrial applicability**; citations and explanations supporting such statement

Document D1 is regarded as being the closest available prior art to the subject-matter of claim 1. Document D1 shows the following features thereof (the references in parentheses applying to this document):
A medical implant (col.4, line 24) comprising
an oscillator monitoring means (Fig. 1 (60) for monitoring the function of an oscillator means (14) in the medical implant,
said oscillator means producing periodic pulses (Fig.1, (A), (B), (C)) for use in the operation of the medical implant (col. 4, lines 63 ff),
said oscillator monitoring means (60) detecting a deviation in said function and providing a deviation signal (Fig. 1, output of (60); Fig. 5, (164)) indicating said deviation detection (col. 11, lines 50 ff.);

and a measuring means (Fig. 1: LEAD 1 and (30)) for obtaining at least one physiological parameter (IEGM, col. 5, lines 30 - 36) emanating from the human body, and said physiological parameter comprising a time component (it is obvious for the person skilled in the art that an IEGM comprises time components, e.g. the QT-interval).

Claim 1 is novel according Art. 33(2) PCT as the subject matter of claim 1 differs from the known medical implant of document D1 in that the implant of D1 uses a second oscillator as a reference when frequency checking the oscillator means. Furthermore the implant of D1 uses the measured physiological parameter to inhibit or trigger an output of the implant. Claim 1 suggests on the other hand to use an electric signal related to a time component of the physiological parameter to detect a deviation in the function of the oscillator means.

The problem to be solved by the present invention may therefore be regarded as "how to provide an alternative solution for monitoring the function of an oscillator means in a medical implant".

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reason: The use of a timing component from a physiological parameter, which is already measured and available as an electrical signal within the medical implant, for the purpose of a deviation detection in an oscillator of the medical implant cannot be derived from the available prior art.

In conclusion, claim 1 appears to satisfy the requirement of Article 33(3) PCT (inventive step).

Claims 2 to 16 define further preferred features of the device of claim 1 and thus also satisfy Article 33 (2)-(4) PCT.

Re Item VII

Imprecise statement

The vague and imprecise statement "the scope of the present invention" in the

description on page 7, lines 3 - 4, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

MEDICAL IMPLANT

Technical field of the invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to a medical implant comprising oscillator monitoring means for monitoring the function of oscillator means in the medical implant, and a method of monitoring the function of oscillator means in a medical implant, said medical implant preferably being a heart stimulator.

Technical background and prior art

For modern electronic circuits, it is generally essential to provide an accurate clocking signal in order to synchronise the different electronic functions of the circuit. Generally, a single master timing source, such as an oscillator, is used to produce a periodic signal at a fixed frequency. An accurate clock signal is imperative for a proper function of the electronic circuit. If the frequency of the periodic signal deviates from its predetermined frequency, the circuit will not function in the intended manner.

Within the field of medical implants, i.e. heart stimulators, the master timing source is generally an oscillator. Heart stimulators are life supporting, therapeutic medical devices that are surgically implanted and remain within a person's body for years. Thus, a need exists for monitoring and checking the master oscillator of the heart stimulator to determine if the frequency of the oscillator periodic signals deviates from its predetermined clock frequency and to handle such deviation if it occurs.

US 4,590,941 discloses a cardiac pacer comprising stimulating logic for producing an output stimulating signal, the stimulating logic including a crystal os-

cillator and a digital circuit for producing the pacing logic of the pacer. The pacer further comprises a continuously operating RC oscillator and a frequency checking circuit. The RC oscillator is an emergency oscillator continuously producing an output at a predetermined acceptable frequency and a predetermined pulse width. The crystal frequency is tested by the frequency checking circuit using the output of the RC oscillator. The pacer further comprises gating means for substituting the output of the RC oscillator for the output of the stimulating logic upon detection of failure of the crystal oscillator.

Hence, the reference parameter used for continuously testing the frequency of the crystal oscillator is the output frequency of the RC oscillator. This requires a continuous operation of the RC oscillator. Furthermore, the frequency checking circuit requires a reliable output from the RC oscillator in order to provide a safe and accurate result. Otherwise, the frequency of the crystal oscillator could be considered to deviate from the correct frequency when, in fact, it is the frequency of the RC oscillator that deviates from the predetermined frequency.

Summary of the invention

It is therefore an object of the present invention to provide a method, and a medical implant using said method, for detecting with improved reliability a frequency deviation of the output frequency of an oscillator in a medical implant.

This object is achieved in accordance with the present invention by providing a medical implant and a method having the features defined in the independent claims. Preferred embodiments are defined in the dependent claims.

The invention is based on using a physiological parameter emanating from the human body for monitoring the

status of the output frequency of a timing circuit in a medical implant. Hence, deviations in the output frequency of the timing circuit are detected by using the physiological parameter as a reference. Preferably, the timing circuit is an oscillator.

By using a physiological parameter for detecting a deviation in the output frequency of an oscillator, use is made of a parameter that is always present, i.e. the physiological parameter can be used for detecting a frequency deviation regardless of whether there is a fault in the electronic circuitry or not. This might not always be the case when a parameter obtained from within the electronic circuitry is used for said deviation detection. In fact, a deviation in the output frequency of a main oscillator in an electronic circuit, can cause resulting effects in the electronic circuitry making components within the circuitry unsuitable, or unusable, for providing a reference parameter for said monitoring.

Furthermore, the problem described in relation to prior art regarding the risk of misinterpreting the result, i.e. the output frequency one oscillator being considered to deviate when the deviation occurs in the output frequency of the other oscillator, is eliminated according to the present invention. This is due to the fact that the monitoring of an oscillator does not involve any other oscillator that might be comprised in the medical implant.

The physiological parameter used for the monitoring of the output frequency of the oscillator contains a time component. The time component of the physiological parameter is used for monitoring deviation of the frequency from a permitted value or range.

As is obvious to a person skilled in the art, any physiological parameter varies over time. Therefore, an exact time value can not be obtained from a physiological parameter. However, the typical oscillator used as a

main oscillator in a medical implant is a crystal oscillator, which is calibrated before encapsulation through mechanical treatment. It is well known that, if the output frequency of a crystal oscillator deviates from its intended frequency, it deviates drastically, the output frequency for instance changing to zero or multiples of the intended frequency. Thus, a physiological parameter can be used for monitoring the status of an oscillator, even though said parameter varies slightly over time.

Further details and aspects of the invention will become apparent from the following detailed description of embodiments of the invention, reference being made to the accompanying drawings.

Brief description of the drawings

Figure 1 illustrates in block diagram form a medical implant comprising oscillator monitoring means according to the present invention.

Figure 2 illustrates in block diagram form the measuring means shown in figure 1.

Figure 3 illustrates in block diagram form the monitoring means shown in figure 1.

Figure 4 illustrates in block diagram form a specific embodiment of the present invention.

Figure 5 illustrates in circuit diagram form a watch dog circuit according to the embodiment shown in figure 4.

Detailed description of preferred embodiments

With reference to figure 1, there is shown in block diagram form a medical implant 1 comprising an oscillator 2, oscillator monitoring means 10, measuring means 20 and deviation handling means 30. As apparent to the person skilled in the art, a medical implant, i.e. a heart stimulator, comprises and is connected to a number of additional elements that are essential for the intended function of the implant, e.g. a pulse generator,

telemetry means, etc. However, the functions of these elements are well known within the art and the illustration and description thereof are therefore omitted. Thus, only parts of the medical implant directly related to the present invention are illustrated and described herein.

As illustrated in figure 2, the measuring means 20 preferably comprises sensor means 21, for sensing, or recording, a chosen physiological parameter P, and detecting means 25, for detecting characteristics of the chosen physiological parameter P. The sensor type can be chosen among several alternatives and is dependent on the chosen physiological parameter P. The sensor means 21 is connected to the detecting means 25, but is not necessarily contained within the medical implant 1, contrary to what is illustrated in figure 1. According to embodiments of the invention, the sensor means 21 is situated externally of the medical implant and is connected to the medical implant through electric leads (not shown).

The detecting means 25 is arranged for detecting characteristics of the physiological parameter P comprising the chosen time component, the characteristics being dependent on the type of parameter sensed, and for generating an electric signal E containing or being related to these characteristics. The sensor means 21 and the detector means 25 do not necessarily have to be separate units, instead they can be comprised as a single unit for sensing the physiological parameter P and for generating the electric signal E.

With reference to figure 3, the oscillator monitoring means 10 preferably comprises signal processing means 11, receiving the electric signal E and oscillator output frequency F (i.e. the periodic pulses produced by the oscillator), and comparing means 15, receiving an oscillator status signal S supplied by the signal proc-

essing means 11 and a predetermined reference signal Ref, which can be in the form of a value, range, or a template. Preferably, the electric signal E representative of the physiological parameter P is used by the signal processing means 11 for generating an oscillator status signal S that reflects the status of the oscillator output frequency F.

The oscillator status signal S can be directly indicative of the output frequency F, e.g. by representing the number of pulses produced by the oscillator 2 during a chosen time interval, or be indirectly indicative of the output frequency F, e.g. by presenting a signal representing a parameter, which in turn is directly dependent on the output frequency F.

The oscillator status signal S is supplied to the comparing means 15 for comparing the status signal S with a predetermined reference signal Ref. The reference signal used for said comparison could be a value, a range or a template of some sort, depending on the nature of the physiological parameter. As a result of said comparison, a deviation signal D is produced indicating whether the output frequency of the oscillator is within a permitted value or range, or not.

Preferably, the oscillator status signal S is in the form of a value representing the output frequency F of the oscillator, and the reference signal Ref is in the form of two threshold values representing the permitted maximum and minimum frequencies of the oscillator. In such a case, the deviation signal D preferably has two possible values, the output frequency F lies within the permitted range, or the output frequency F is outside the permitted range. According to an alternative embodiment, the oscillator status signal S represents the morphology of a physiological parameter P, e.g. heart sounds, and the comparing means 15 compares the oscillator status signal S to a template using neural

networks. Several other alternatives regarding the form of the oscillator status signal S and the reference signal Ref are conceivable without departing from the scope of the present invention.

According to preferred embodiments of the present invention, the physiological parameter P used for the monitoring of the status of the oscillator 2 is the electrical signal emitted by active cardiac tissue, which for ease of description hereinafter will be referred to as the cardiac signal C. The cardiac signal C is typically recorded through cardiac electrodes and the graphic depiction of the signal is normally referred to as an electrocardiogram (ECG). If the electrodes are placed on or within the heart, the graphic depiction is referred to as an intracardiac electrogram (IEGM). The characteristic portions of the ECG or IEGM are very well known and will be referred to without further description in detail.

The time component used for the oscillator monitoring preferably is obtained within a cardiac cycle, particularly within the systolic phase thereof. The physiological parameters could for instance be related to the width of the QRS-complex or to the QT-interval (i.e. related to the ejection phase of the heart). The parameters related to the width of the QRS-complex preferably is derived from the IEGM by means well known in the art. The parameters related to the QT-interval may be derived directly from the IEGM or indirectly by means of pressure measurements in the ventricle, by impedance measurements, by means of heart sounds such as the valve sounds. Corresponding methods are well known in the art. Said comparison is preferably performed repeatedly for achieving a continuous monitoring of the oscillator status using the IEGM or corresponding parameters of the latest heart beat.

With reference to figures 4 and 5, the most preferred embodiment of the present invention will now be described. The cardiac electrical activity (i.e. the cardiac signal C) is sensed through at least one cardiac electrode 22 positioned within the patient's heart. The sensed parameter is supplied, now in the form of an IEGM, to the detecting means 25, in this case constituting a QRS detector 26 and a T-wave detector 27 that both receives the IEGM. The QRS detector 26 detects the QRS complex, i.e. the R-peak, and the T-wave detector 27 consequently detects the T-wave. The detectors 26, 27 generate a QRS-detector output signal Q and a T-wave detection signal T, respectively, in the form of a short pulse when the respective event is detected.

The chosen time component of the physiological parameter P used for said monitoring is in this case the time period between the QRS complex and the T-wave of the IEGM, said time period hereinafter being referred to as the QT-interval. The QT-interval is relatively easy to measure and use is preferably made of the existing cardiac electrode(s) used for stimulating (and sensing) in the ventricle for sensing the QRS complex and the T wave. The QT-interval typically varies within the range of 250 to 350 ms and is substantially independent of the output of the main oscillator. There may be some, but very small, correlation since the QT-interval depends upon the stimulation rate. The QT-interval is therefore very useful and is preferred as the physiological parameter used for said monitoring.

Returning to figure 4, the electric signal E, being divided into the QRS detection signal Q and a T-wave detection signal T, is supplied via a watch dog circuit 40 to the signal processing 11, the signal processing means 11 here being a counter 12. The watch dog circuit 40 is provided between the detecting means 25 and the counter 12 for handling a specific situation and will be de-

scribed in detail below with reference to figure 5. The function of the counter 12 is as follows. The counter 12 will be reset by a QRS event, i.e. a pulse in the QRS detection signal Q. The pulse will also trigger the counter 12 to start counting received periodic pulses F produced by the main oscillator 2. At the reception of a pulse in the T-wave detection signal T, the counter 12 will stop counting and the counted number of received pulses during the QT-interval will be sent as the oscillator status signal S to the comparing means 15.

The QT-interval will then be compared, by the comparing means 15, with predefined QT-interval threshold values provided by a reference signal Ref, corresponding to the QT-interval at the maximum and minimum, respectively, permitted main oscillator frequency. The T-wave detection signal T is also provided to the comparing means 15 via a delay circuit 50 for triggering said comparison. The delay circuit 50 ensures that sufficient time has elapsed for the calculation to be completed before the triggering of the comparison. The result of the comparison will be supplied as a deviation signal D indicating whether the output frequency F of the oscillator 2 lies within the permitted range, or not.

With reference now to figure 5, the function of the watch dog circuit 40 will be described. If no signal for triggering the comparison and providing a deviation signal, i.e. the T-wave detection signal T, is provided to the comparing means 15, no comparison would be carried out and the information contained in the deviation signal D would not change to describe the current status, provided that the oscillator status has changed. One attempt to solve this problem could be to perform a comparison after a given time delay without reception of the T-wave detection signal T. However, this would require some sort of timing signal to be provided. If no output pulses are received from the oscillator 2 this

would not be indicated in the deviation signal D if no T-wave detection signal T for triggering the comparison is received from the T-wave detector, i.e. if the patient has no intrinsic rate.

In order to solve this potentially serious problem, the watch dog circuit 40 is provided. The watch dog circuit 40 is provided for delivering a pulse after a predetermined time in the absence of a QRS detection signal Q and a T-wave detection signal T. The circuit 40 comprises a first resistor 41; a second resistor 42; a transistor 43; a capacitor 44; a first buffer circuit 45; a second buffer circuit 46; a first OR-gate 47; and a second OR-gate 48. As is apparent from the figure, when a QRS detection signal Q or a T-wave detection signal T, respectively, are received, these signals are supplied via the respective OR-gates 47, 48 as QRS detection signal Q^I and T-wave detection signal T^I, respectively. The respective detection signals Q, T passes the watch dog circuit essentially unchanged, even though the output detection signals Q^I, T^I supplied to the comparing means have a difference reference character in the figure.

If there would be a no QRS detection signal Q, there would be no T-wave signal T. If there is a QRS signal, there will be a T-wave signal. Thus, the situation to be considered is the loss of both the QRS and the T-wave detection signals. The capacitor 44 is connected to ground and will be charged by the voltage supplied via the second resistor 42. The time constant of the circuit is dependent of the second resistor 42 and the capacitor 44. The charging of the capacitor 44 increases the potential of the side connected to the first buffer circuit 45. When the potential reaches a predefined level, the buffer circuit 45 goes high. If a QRS detection signal Q is supplied to the watch dog circuit 40, this will cause the transistor 43 to short-circuit

and discharge the capacitor 44 and the potential of the first buffer circuit 45 will drop to zero before the first buffer circuit 45 goes high. However, if no QRS detection signal Q is supplied, a pulse is supplied by the first buffer circuit 45 to the first OR-gate 47 and, via the second buffer circuit 46, to the second OR-gate 48.

Then, the pulse will be supplied in place of the QRS and T-wave detection signals Q^I, T^I to the counter, with a slight delay for the T-wave detection signal T^I caused by the second buffer circuit 46, and a low pulse count, corresponding to the delay caused by the second buffer circuit 46, will be sent to the comparing means 15 as the status oscillator signal S. The T-wave detection signal T^I will also trigger the comparison. Since the value of the status oscillator signal S will not lie within the predefined permitted range, the deviation signal D will indicate that the output frequency F of the oscillator has deviated from the permitted range.

According to another embodiment of the present invention the width of the QRS complex is measured and used for said monitoring. The variation of the QRS width is somewhat greater than that of the QT-interval. Like the QT-interval, this parameter can easily be measured using the cardiac electrode(s) and requires no additional electronic circuitry. Preferably, the number of output pulses from the oscillator to be monitored is counted, preferably using counting means 12 comprised in the signal processing means 11, during the duration of the QRS, and is supplied as an oscillator status signal S.

Another example of using the IEGM for said monitoring is using the paced depolarisation integral (PDI). The PDI is a well-known parameter that denotes the integral of the QRS complex of the IEGM from the base line. The PDI essentially is constant from beat to beat. Pref-

erably, PDI is obtained using integrating means comprised in the signal processing means 11. In similarity with the above embodiments, using the PDI requires no additional sensors (e.g. electrodes) or circuitry. The variation of the PDI corresponds with the QRS width, and the obtained value of the PDI is supplied as the electric signal E, as illustrated in figure 3. Since the calculated value of the PDI varies in dependence on the output frequency F, the oscillator status signal S is based on the electric signal E, comprising the PDI value, and the output frequency F. The integral is calculated by means of the output frequency and the value of the PDI will deviate from the normal value if the frequency deviates from the standard value. If the oscillator status signal S is determined to be outside predetermined threshold values, this will indicate that the oscillator frequency deviates from the permitted range.

Other physiological parameters are envisioned for monitoring the status of the main oscillator 2. According to one alternative embodiment the physiological parameter is the heart sounds or sound waves produced when the heart operates, e.g. sounds associated with valve opening and closing and diastolic filling sounds. As is the case with the characteristics of the ECG or the IEGM, the sound waves correspond to specific events in the cardiac cycle and have a characteristic morphology. Thus, the time information obtained from heart sounds is considered to be as accurate, or vary as little, as the QT-interval.

The morphology may be analysed in several ways. According to a first example of alternative embodiments of the present invention, the number of pulses output by the oscillator between detected specific events in the sound waves of the cardiac cycle is counted and supplied

as an oscillator status signal S for subsequent comparison with threshold values Ref.

There are several ways of detecting heart sounds, including using a microphone or an accelerometer. The advantage of using an accelerometer is that accelerometers are often used in rate responsive heart stimulators for determining the level of physical activity of the patient. Thus, such an accelerometer could also be used for detecting heart sounds, and no additional sensor means would be required. If the heart sounds are detected by a microphone, however, then an additional component that normally is not found in a medical implant or heart stimulator is used. There may also be a problem in detecting the heart sounds as distinctly as is required for determining the time for specific events of the cardiac cycle, due to the interference of the external environment.

According to preferred embodiments of the invention, the medical implant comprises a back-up timing circuit (not shown), preferably an oscillator, for acting as a main timing circuit, or oscillator, when the output frequency of the original main oscillator 2 deviates outside the predefined permitted range. The back-up oscillator is preferably an RC oscillator, or a current controlled oscillator, for the purpose of providing a back-up timing source that is small and light in weight.

As is shown in figure 1, deviation handling means 30 is connected to the monitoring means 10, preferably to the comparing means 15, for handling a deviation in the output frequency F of the main oscillator 2. The handling means 30 is activated when the received deviation signal D indicates a deviation, i.e. when the output frequency F deviates outside the permitted range. The handling means 30 comprises the back-up oscillator (not shown), for producing periodic pulses normally not being used in the operation of the medical implant, and

switching circuitry (not shown) connected to the main and the back-up oscillator for switching between the normal state and a deviation state. The switching between the respective state is performed by disconnecting the main oscillator 2 and by simultaneously connecting the back-up oscillator such that the periodic pulses produced in the back-up oscillator are used in the operation of the medical implant. According to preferred embodiments of the invention, the status of the back-up oscillator is also monitored by the monitoring means of the present invention, in the manner described above. However, since the back-up oscillator is normally not used for the normal function of the medical implant, the monitoring of the back-up oscillator can be performed regularly but at a substantially lower rate than the monitoring of the main oscillator, which should be performed continuously.

According to an alternative embodiment of the invention, the deviation handling means 30 comprises alarm means for providing an alarm signal when the deviation signal D indicates that the output frequency F of the oscillator 2 deviates outside the permitted range. The alarm signal could be in the form of a signal that can be observed or sensed by the patient, e.g. an acoustic signal, or a signal that is transmitted to an external apparatus using the telemetry functions generally provided in a medical implant. The alarm signal could be provided in combination with said switching to the back-up oscillator, or as a separate action, e.g. indicating that the patient should contact his/her physician but that the need for switching to the back-up oscillator has not arisen. A detected deviation in the output frequency of the back-up oscillator, when functioning as such, is preferably handled by the handling means 30 activating an alarm signal. Switching to the other oscillator will not be necessary since the back-up oscillator

in this case is not involved in the normal operation of the medical implant.

The timing circuits used in the medical implant according to present invention are preferably oscillators, wherein as the main oscillator use is preferably made of a crystal oscillator, due to the superior reliability of crystal oscillators.

CLAIMS

1. A medical implant (1) comprising oscillator monitoring means (10) for monitoring the function of oscillator means (2) in the medical implant (1), said oscillator means (2) producing periodic pulses for use in the operation of the medical implant (1), said oscillator monitoring means (10) detecting a deviation in said function and providing a deviation signal (D) indicating said deviation detection; and

measuring means (20) for obtaining at least one physiological parameter (P) emanating from the human body, said parameter comprising a time component, and for generating an electric signal (E) related to said time component, said oscillator monitoring means (10) being connected to the measuring means (20) for using said electric signal (E) for said deviation detection.

2. The medical implant (1) according to claim 1, wherein the monitoring means (10) comprises signal processing means (11) for processing the electric signal (E) and for generating an oscillator status signal (S), and comparing means (15) for comparing said oscillator status signal (S) with a reference signal (Ref).

3. The medical implant (1) according to claim 2, wherein said measuring means (20) comprises sensor means (21) for sensing the physiological parameter (P).

4. The medical implant (1) according to claim 3, wherein the sensor means (21) comprises cardiac electrodes (22) for receiving cardiac signals (C) emanating from cardiac electrical activity, said cardiac signals (C) constituting the physiological parameter (P) and being representative of the time component and forming an IEGM.

5. The medical implant (1) according to claim 4, wherein said measuring means (20) comprises detector

means (25) connected to the sensor means (21) for detecting the QRS complex and the T-wave of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS detection signal (Q), and a T-wave detection signal (T).

6. The medical implant (1) according to claim 5, wherein said signal processing means (11) comprises counting means (12), said counting means (12) being connected to said detector means (25) for receiving the QRS and the T-wave detection signals (Q, Q^I, T, T^I), and to said oscillator means (2) for receiving the periodic pulses,

said counting means (12) being arranged for counting the number of periodic pulses received between the reception of the QRS detection signal (Q, Q^I) and the T-wave detection signal (T, T^I), and for outputting said number as said oscillator status signal (S).

7. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS signal indicating the beginning and the end of the QRS complex; and

said signal processing means (11) comprises counting means (12) connected to said detector means (25) for receiving the QRS signal, and to said oscillator means (2) for receiving the periodic pulses, said counting means (12) being arranged for counting the number of periodic pulses received between the beginning and the end of the QRS complex, and for outputting said number as said oscillator status signal (S).

8. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex and the amplitude of theQRS, and for generating said electric signal (E); and

said signal processing means (11) comprises integrating means connected to said detector means (25) for receiving the electric signal (E), said integrating means being arranged for integrating said amplitude during the QRS complex, and for outputting said integration as said oscillator status signal (S).

9. The medical implant (1) according to claim 3, wherein

the sensor means (21) comprises at least one microphone for converting sensed periodic heart sounds into an electric periodic sound signal, said heart sounds constituting the physiological parameter (P);

the measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting chosen characteristics of the sound signal, and for generating said electric signal (E) indicating said characteristics; and

the signal processing means (11) is arranged for outputting said oscillator status signal (S) based on said electric signal (E).

10. The medical implant (1) according to any one of claims 2-9, wherein the reference signal (Ref) comprises predefined threshold values, and wherein the monitoring means (10) provides the deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

11. The medical implant (1) according to any one of the preceding claims, comprising deviation handling means for handling a deviation in said oscillator means, said deviation handling means being connected to said

monitoring means (10) for reception of said deviation signal (D).

12. The medical implant (1) according to claim 11, wherein said deviation handling means comprises

a back-up system including back-up oscillator means for producing periodic pulses, said periodic pulses in a normal state not being used in the operation of the medical implant (1), and

switching circuitry connected to said main and back-up oscillator means for switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

13. The medical implant (1) according to claim 12, wherein said monitoring means (10) further is arranged for detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating the detection of such a deviation, and wherein said deviation handling means is arranged for handling a deviation in said back-up oscillator means.

14. The medical implant (1) according to claim 12 or 13, wherein said back-up oscillator means is an RC oscillator.

15. The medical implant (1) according to any one of claims 11-14, wherein said deviation handling means comprises alarm means for producing an alarm signal when the received deviation signal (D) indicates a deviation.

16. The medical implant (1) according to any one of the preceding claims, wherein said oscillator means (2) is a crystal oscillator.

17. A method of monitoring the function of oscillator means (2) in a medical implant (1), preferably a heart stimulator, the method comprising

obtaining at least one physiological parameter (P) emanating from the human body, said physiological parameter (P) containing a time component; and

using said physiological parameter (P) in monitoring the function of said oscillator means.

18. The method according to claim 17, wherein the step of monitoring said function comprises

detecting a deviation in said function; and

providing a deviation signal (D) indicating said deviation detection.

19. The method according to claim 17 or 18, wherein the step of obtaining said physiological parameter (P) comprises

sensing said physiological parameter (P); and

generating an electric signal (E) based on said physiological parameter (P); and

wherein the step of detecting said deviation comprises

processing the electric signal (E) and thereby generating an oscillator status signal (S); and

comparing said oscillator status signal (S) with a reference signal (Ref).

20. The method according to any one of claims 17-19, wherein said physiological parameter (P) is a cardiac signal (C) emanating from cardiac electrical activity, said cardiac signals (C) being representative of the time component and forming an IEGM.

21. The method according to claim 20, wherein the step of processing the electric signal (E) comprises

detecting the QRS complex of the IEGM;

detecting the T-wave of the IEGM;

receiving periodic pulses from said oscillator means;

counting the number of received periodic pulses between said detection of the QRS complex and said detection of the T-wave; and

outputting said number as the oscillator status signal (S).

22. The method according to any one of claims 19-21, wherein said reference signal (Ref) comprises predefined threshold values; and

wherein the step of comparing said oscillator status signal (S) with a reference signal (Ref) comprises

providing a deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

23. The method according to any one of claims 18-22, further comprising the steps of

receiving the deviation signal (D) provided by the comparing means (15);

handling a deviation in said oscillator means (2) when the received deviation signal (D) indicates a deviation.

24. The method according to claim 23, wherein the step of handling a deviation comprises

activating a back-up system comprising back-up oscillator means for generating periodic signals, said periodic signals in an normal state not being used for the operation of the implant; and

switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

25. The method according to claim 24, further comprising the steps of

detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating detection of such a deviation; and

handling a deviation in said back-up oscillator means.

26. The method according to any one of claims 24-25, wherein the step of handling a deviation comprises activating an alarm signal.

Fig. 1

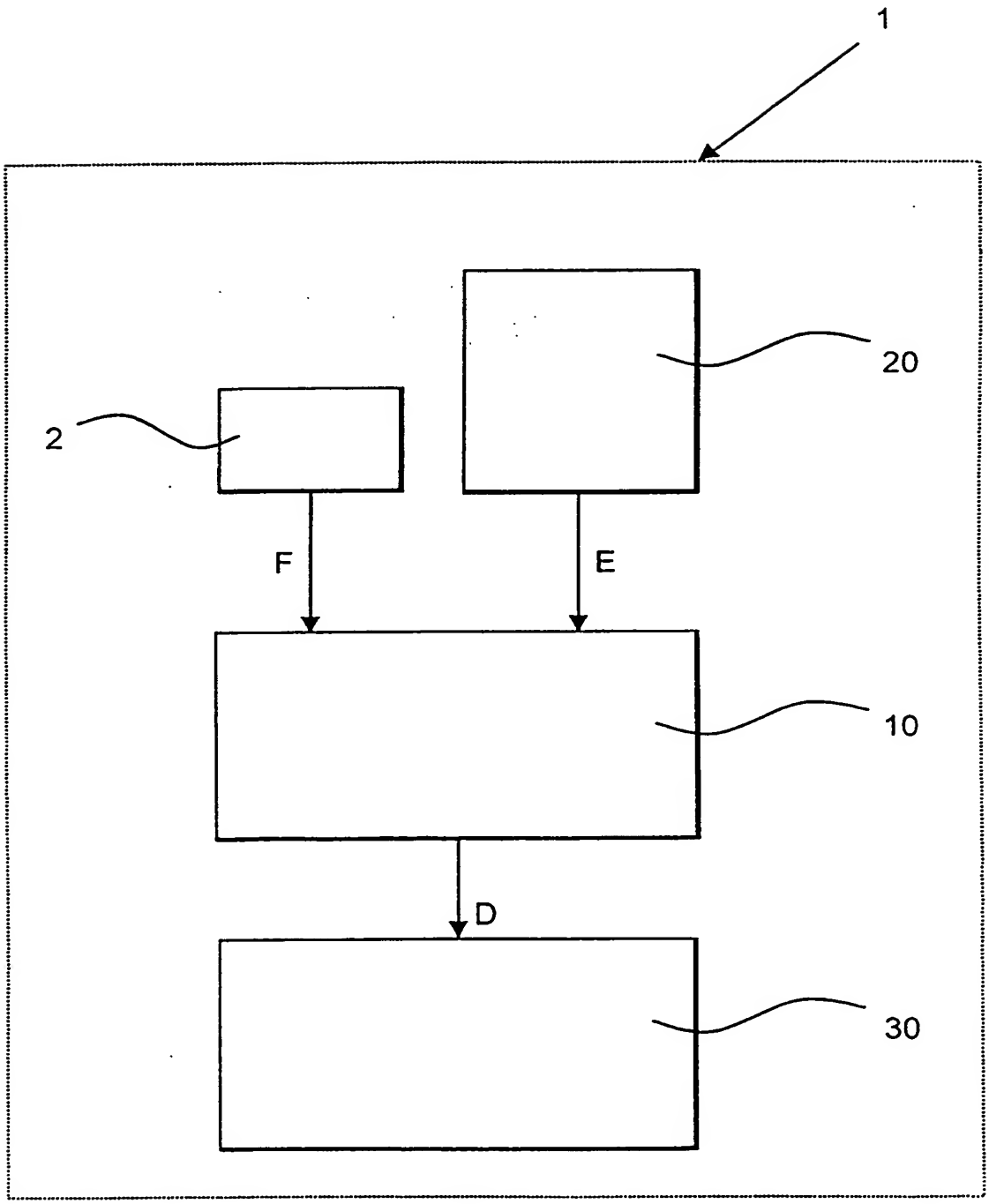


Fig. 2

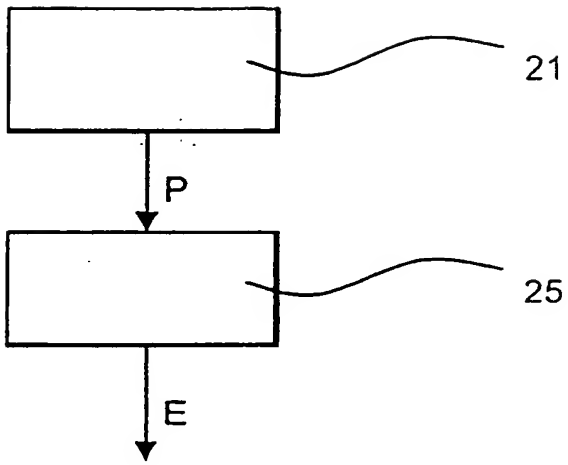


Fig. 3

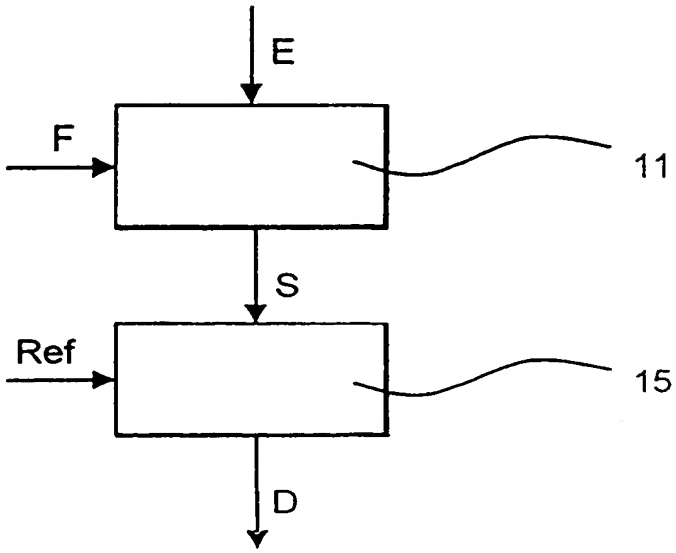


Fig. 4

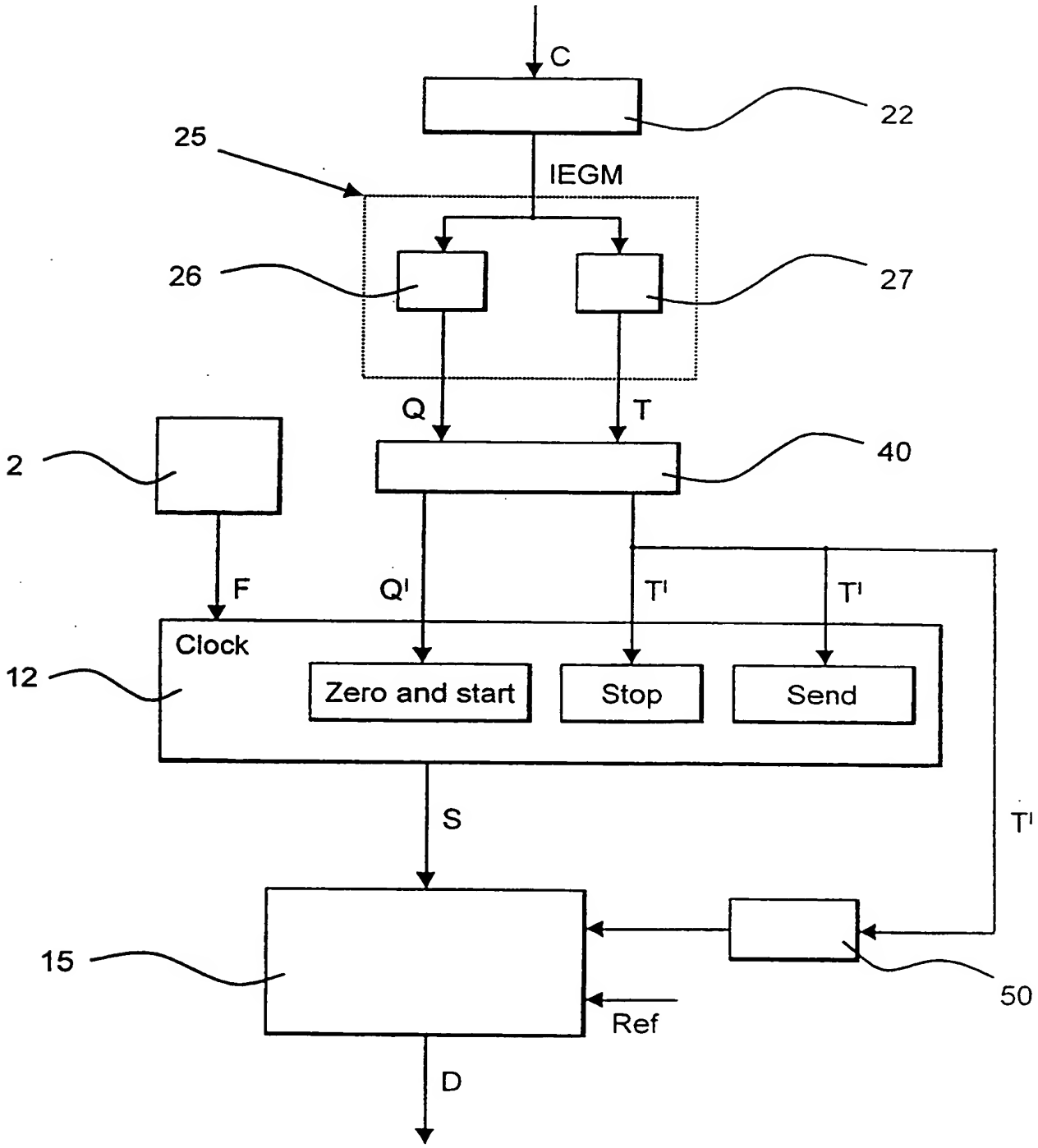
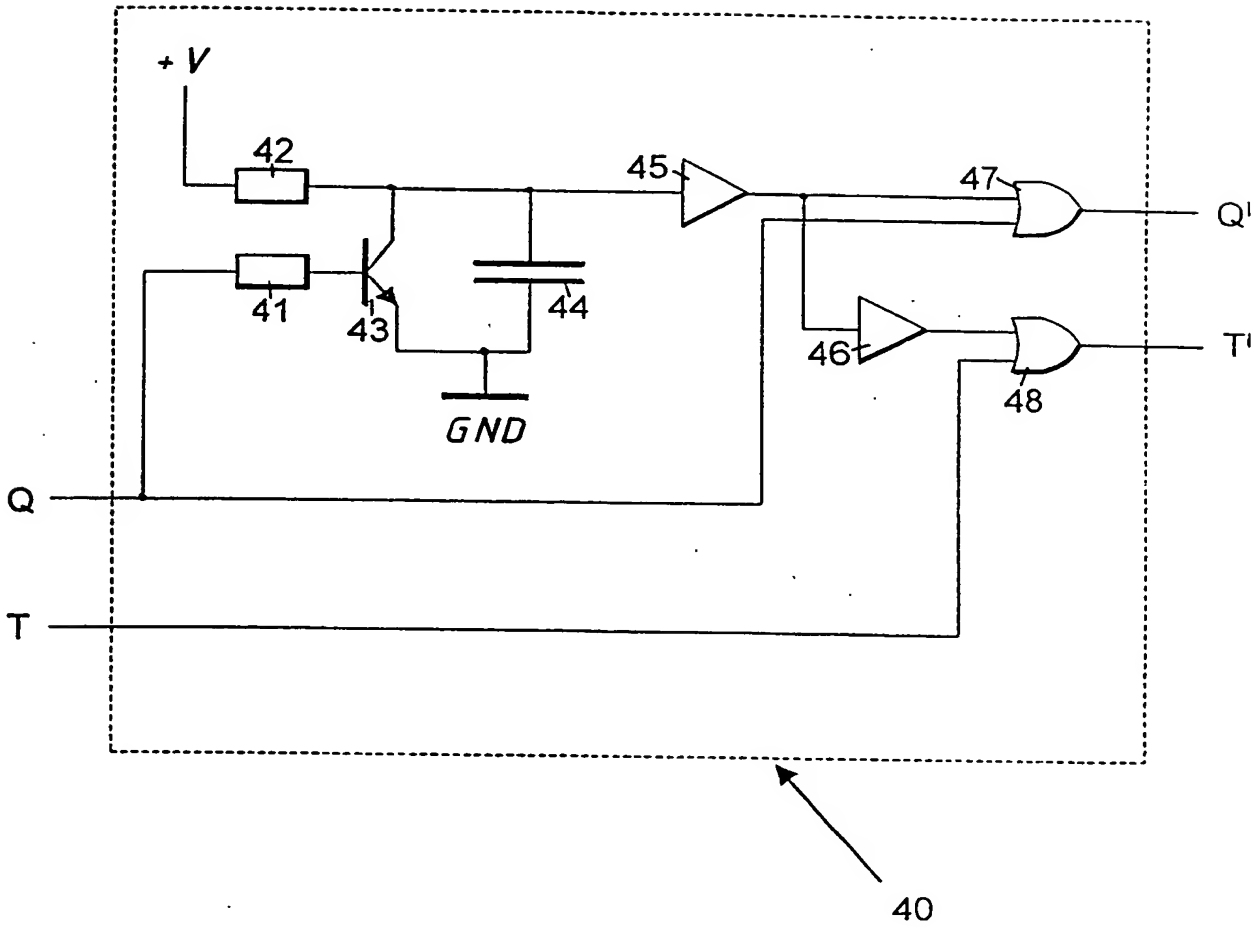

C
22
25
IEGM
26
27
Q
T
2
40
F
Q'
T'
T'
Clock
12
Zero and start
Stop
Send
S
T'
15
50
Ref
D

Fig. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01025

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 1599231 A (MEDTRONIC INC.), 30 Sept 1981 (30.09.81), page 2, line 1 - line 23 --	1-26
A	DE 2539592 A1 (INFORM ELEKTROMEDIZINISCHE GERÄTE GMBH), 10 March 1977 (10.03.77), page 1, line 1 - page 2, line 15 --	1-26
D,A	US 4590941 A (STANLEY H. SAULSON ET AL), 27 May 1986 (27.05.86), abstract -- --------	1-26

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 Sept 2000	19 -09- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/mj Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/00

International application No.
PCT/SE 00/01025

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 1599231 A	30/09/81	AR 224616 A	30/12/81
		AU 519527 B	10/12/81
		AU 3645478 A	29/11/79
		BE 868057 A	02/10/78
		BR 7803758 A	09/01/79
		CA 1101935 A	26/05/81
		DE 2825626 A,C	21/12/78
		FR 2394281 A,B	12/01/79
		IT 1105721 B	04/11/85
		IT 7849827 D	00/00/00
		JP 1356909 C	13/01/87
		JP 54006388 A	18/01/79
		JP 61025387 B	16/06/86
		NL 7806336 A	15/12/78
		SE 439732 B,C	01/07/85
		SE 7806319 A	14/12/78
		US 4164945 A	21/08/79
DE 2539592 A1	10/03/77	FR 2322616 A	01/04/77
US 4590941 A	27/05/86	US 4437466 A	20/03/84